

PATENTS
REB-001 Div

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant : Rebecca Gomez

Application No. : 10/696,258 Confirmation No. : 7051

Filed : October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS

Art Unit : 3769

Examiner David M. Shay

New York, New York 10036
August 20, 2010

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 C.F.R § 41.37

Sir:

Appellant is filing this Appeal Brief in support of the appeal from the final rejection of claims 13-15, 19, 21, 27, 33-36, and 38-44 in the Final Office Action dated February 22, 2010 ("the Final Office Action"). A Notice of Appeal for this case is being filed concurrently herewith.

The Director is hereby authorized to charge \$270.00 to Deposit Account No. 50-0540 in payment of the filing fee

required under 37 C.F.R. § 41.20(b)(2). The Director is also hereby authorized to charge any additional fees that may be due in connection with this Appeal Brief, or credit any overpayment of the same, to Deposit Account No. 50-0540.

In view of the arguments and authorities set forth below, the Board should find the rejection of claims 13-15, 19, 21, 27, 33-36, and 38-44 to be in error, and the Board should reverse the rejection.

This Brief has the following appendices:

Claims Appendix

Appendix A: Copy of claims 13-15, 19, 21, 27, 33-36, and 38-44 involved in this appeal;

Evidence Appendices

Appendix B: Copy of the Final Office Action dated February 22, 2010;

Appendix C: Copy of Rosenberg Non-Patent Literature: "The Dilemma of Pilonidal Disease"; *Diseases of the Colon and Rectum*: May-June, 1977;

Appendix D: Copy of the Declaration under 37 C.F.R. § 1.132 of Doctor Jeffrey Stephen Freed, originally filed by appellant on November 12, 2009;

Appendix E: Copy of the Declaration under 37 C.F.R. § 1.132 of Doctor Sandra L. Curet, originally filed by appellant on November 12, 2009;

- Appendix F: Copy of the Declaration under 37 C.F.R.
§ 1.132 of Doctor Randolph M.
Steinhagen, originally filed by
appellant on November 12, 2009; and
- Appendix G: Copy of the Declaration under 37 C.F.R.
§ 1.132 of Maria Isabel Suárez,
originally filed by appellant on
November 12, 2009.

Related Proceedings Appendix

None.

- (i) Real Party In Interest
Appellant respectfully advises the Board the real party in interest in the above-identified patent application is the appellant and inventor of the claimed device, Rebecca Gomez.
- (ii) Related Appeals and Interferences
Appellant respectfully advises the Board that there are no other appeals or interferences known to appellant or her legal representatives that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.
- (iii) Status of Claims
Claims 1-12, 16-18, 20, 22-26, and 37 are cancelled.
Claims 28-32 are withdrawn from consideration. Claims 13-15, 19, 21, 27, 33-36, and 38-44 are finally rejected in this

application and are on appeal. Claims 13, 14, 33, 40, and 41 have been objected to in this application and are on appeal.

(iv) Status of Amendments

Appellant has not submitted any amendments pursuant to 37 C.F.R § 1.116 or in reply to the Final Office Action, from which this appeal is being sought.

(v) Summary of Claimed Subject Matter

Appellant's independent claims 13, 33, and 40 are directed to apparatuses for relieving discomfort caused by swollen tissue ailments. In particular, each claim includes a strip of material that is operable to separate swollen tissue from non-swollen tissue. For example, the swollen tissue may be caused by a hemorrhoids ailment (see, e.g., appellant's specification, page 9, lines 12-15). The strip of material is "crescent shaped" and is either "substantially planar" (claims 13 and 33) or "substantially contained within a single plane" (claim 40). In other words, if appellant's claimed invention were laid down on a surface, it could lie flat against this surface and appear crescent shaped from a top view (see, e.g., appellant's FIG. 3, tape 30). An adhesive is applied to the strip such that the strip is operable to be applied to a person's body in a manner that separates the swollen tissue from the non-swollen tissue when applied.

Support in the specification for claims 13, 33, and 40 may be found in at least the locations indicated in the following tables.

Claim 13	The Specification
Apparatus for relieving discomfort caused by swollen tissue ailments comprising:	See, e.g., specification, page 9, lines 12-16.
a strip of material having first and second ends, wherein: said strip of material is substantially planar,	See, e.g., specification, page 9, lines 1-2 and FIG. 3, tape 30.
said strip of material is crescent shaped,	See, e.g., specification, page 13, lines 27-29 and FIG. 3, tape 30.
said strip of material includes a length and a width, wherein the length is at least twice as long as the width,	See, e.g., specification, FIG. 3, tape 30.
said strip of material having one side that includes an adhesive applied at least to said first and second ends, and	See, e.g., specification, page 14, lines 10-17.
said strip and said adhesive are operable to be applied to a person's body and to separate said swollen tissue from non-swollen tissue when applied	See, e.g., specification, page 14, lines 10-14.

Claim 33	The Specification
An apparatus for relieving discomfort caused by swollen tissue ailments, the apparatus comprising:	See, e.g., specification, page 9, lines 12-16.
a strip of material that is substantially planar and is crescent shaped,	See, e.g., specification, page 13, lines 27-29 and FIG. 3, tape 30.
the strip of material comprising: a first end; a second end; a width; a length, wherein the length is at least twice as long as the width;	See, e.g., specification, FIG. 3, tape 30.
an adhesive applied to a first side of the strip of material; and	See, e.g., specification, page 14, lines 10-14.
a tab, wherein the tab is	See, e.g., specification, page

located on at least one of the first end and the second end; and	13, lines 30-31 and FIG. 3, tab 35 (where FIG. 3 and the specification were amended on February 20, 2009).
wherein the strip is operable to: be applied to a person's body; and separate swollen tissue from non-swollen tissue when applied.	See, e.g., specification, page 14, lines 10-14.

Claim 40	The Specification
An apparatus for relieving discomfort caused by swollen tissue resulting from hemorrhoids, the apparatus comprising:	See, e.g., specification, page 9, lines 12-16.
a first strip comprising: a top surface and a bottom surface, wherein each surface is flat such that the first strip is substantially contained within a single plane;	See, e.g., specification, page 9, lines 1-2 and FIG. 3, tape 30.
two length-wise edges, wherein each length-wise edge is curved such that the shape of the strip is crescent-shaped in form;	See, e.g., specification, page 13, lines 27-29 and FIG. 3, tape 30.
two width-wise edges, wherein each length-wise edge is at least 2 times as long as each width-wise edge; and	See, e.g., specification, FIG. 3, tape 30.
an adhesive applied to at least a portion of the bottom surface, wherein the adhesive is operable to couple the first strip to a person's body in a manner that separates the swollen tissue from non-swollen tissue.	See, e.g., specification, page 14, lines 10-17.

(vi) Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection and objections to be reviewed on this appeal are:

the final rejection of claims 13-15, 19, 21, 27, 33-36, and 38-44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Rosenberg non-patent literature document entitled "The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal Wound" ("Rosenberg");

the final rejection of claims 13-15, 19, 21, 27, 33-36, and 38-44 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement; and

the objection under 35 U.S.C. § 132(a) to the amendment filed on November 12, 2009 as allegedly introducing new matter.

(vii) Arguments

A. The Declarations Submitted Under
37 C.F.R 1.132 Were Improperly Dismissed

On November 12, 2009, appellant submitted into the record four (4) different declarations under 37 C.F.R. § 1.132. One declaration was from Doctor Steinhagen ("Steinhagen's Declaration" - Appendix F), one was from Doctor Freed ("Freed's Declaration" - Appendix D), one was from Doctor Curet ("Curet's Declaration" - Appendix E), and one was from Mrs. Suárez ("Suárez's Declaration" - Appendix G). On pages 2-11 of the Final Office Action, the Examiner reviewed these four declarations. The appellant would like to respond to the Examiner's review of these declarations. In particular,

appellant respectfully submits that these declarations were improperly dismissed without being given proper consideration.

DECLARATIONS ON OBVIOUSNESS

Doctor Freed, Doctor Curet, and Doctor Steinhagen each declared that the differences between appellant's claimed invention and Rosenberg would not have been obvious to one skilled in the art at the time the application was filed (see, e.g., Freed's Declaration, Appendix D, paragraph 9; Curet's Declaration, Appendix E, paragraph 10; and Steinhagen's Declaration, Appendix F, paragraph 9). In response, the Examiner argued that:

the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior device to produce the claimed device, given the teaching of the prior art and the knowledge and level of skill of one or ordinary skill in the art. Thus while Declarant may find "no similarities in the purpose, application, and design" of the two devices, the Examiner has found many (Final Office Action, page 5. Also see, e.g., Final Office Action, pages 9 and 11)

Appellant agrees that the test for obviousness involves whether "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" (See, *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 405 (2007), emphasis added). Moreover, appellant has provided declarations from not just one professional skilled in the art, but from three professionals skilled in the art. Each of these professionals has declared that appellant's claimed invention is not obvious in view of

Rosenberg. Moreover, the three declarants are not merely doctors, but are, respectively, the Chief of the Division of Colon and Rectal Surgery at Mount Sinai Medical Center in New York City, a proctology specialist (i.e., a medical doctor specializing in diseases of the rectum and anus), and a doctor specializing in Gynecology and Obstetrics. As such, each one of these declarants are qualified as a person of ordinary skill in the art while being expertly knowledgeable in the subject matter to which appellant's claimed invention and Rosenberg pertain.

As such, appellant respectfully submits that the Examiner had no basis to overrule and dismiss the declarations of Doctor Steinhagen, Doctor Freed, and Doctor Curet with regards to obviousness by merely reasoning that "the Examiner has found many" similarities between appellant's claimed invention and Rosenberg (see, e.g., Final Office Action, page 5). Rather, appellant respectfully submits that the Examiner has merely noted such alleged similarities through impermissible hindsight reconstruction. As the MPEP and case law states, an obviousness rejection should take "into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made" otherwise such reasoning is impermissible hindsight reconstruction (See, e.g., MPEP § 2145(X)(A), quoting *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971), emphasis added). As shown above, appellant has provided several affidavits evidencing that the knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made was not sufficient to find appellant's claimed invention obvious in view of Rosenberg.

Moreover, as set forth in more detail below, the Examiner has simply ignored the unsatisfied long felt need that

applicant's claimed invention addresses, which is further evidence of non-obviousness (i.e., more than thirty years have passed since Rosenberg was published, and applicant is not aware of a single instance where anyone has modified Rosenberg to produce the results that are achieved by the claimed invention).

In conclusion, the declarations of Doctor Steinhagen, Doctor Freed, and Doctor Curet provide evidence based on the knowledge of persons of ordinary skill in the art that the differences between appellant's claimed invention and Rosenberg are not obvious. The Examiner's noted similarities, which led the Examiner to a conclusion of obviousness, were nothing more than improper hindsight reconstruction. As such, the declarations of Doctor Steinhagen, Doctor Freed, and Doctor Curet, particularly with regards to obviousness, were improperly dismissed.

DECLARATIONS ON ANATOMICAL AREA OF OPERATION

Doctor Freed, Doctor Curet, and Doctor Steinhagen each declared that the purpose of appellant's claimed invention and the purpose of Rosenberg are different, as evidenced by the fact that each operates on a different anatomical area of the patient's body (see, e.g., Freed's Declaration, Appendix D, paragraph 7; Curet's Declaration, Appendix E, paragraph 8; and Steinhagen's Declaration, Appendix F, paragraph 6). For example, Doctor Freed declared that Rosenberg operates on "the presacral skin and subcutaneous tissue of the buttocks to eliminate the natal cleft" while appellant's claimed invention operates "in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue" (see, Freed's Declaration, Appendix D, paragraph 7).

In response, the Examiner argued that while working "in a different anatomical area . . . may be true, it is also true that the 'different anatomical area' is only inches from the area treated by appellant" (Final Office Action, pages 5 and 7; *see also, e.g.*, Final Office Action page 11). However, appellant respectfully submits that this reasoning is a red herring and is insufficient for dismissing the declarations of the doctors. A close distance to the area treated by applicant's invention has no relevance on whether Rosenberg would solve the problems that are solved by applicant's claimed invention. For example, when medically treating a patient, treating an anatomical area that is "only inches" from the target area can have vastly different, and even detrimental, results. As an illustration, if one were to operate on a patient's heart and the desired operation were performed "only inches" away from the target area, this would likely cause severe damage to the patient and would NOT solve the problem the surgery was supposed to address. This would be true even if the "only inches" away were still located somewhere on the patient's heart. Thus, when performing medical treatments, the exact anatomical area of interest should be treated, rather than treating an area that is "only inches" away. This is a perfect example of why the Examiner improperly ignored the three declarations submitted by doctors skilled in the art in this application. As such, appellant respectfully submits that the Examiner's reasoning was insufficient to dismiss the declarations submitted by Doctor Freed, Doctor Curet, and Doctor Steinhagen.

Moreover, in response to Doctor Freed's declaration that Rosenberg operates "to eliminate the natal cleft" while

appellant's claimed invention operates on the "perianal area," (see, Freed's Declaration, Appendix D, paragraph 7), the Examiner cited <http://www.biology-online.org> to define the natal cleft as "the groove or crack between the buttocks that runs from the below the sacrum to the perineum" (see, Final Office Action, page 10). The Examiner then argued that, because of this definition, "it is clear that the instant device and that of Rosenberg are both intended to operate on the same bodily structure" (see, Final Office Action, pages 10-11).

The Examiner's conduct is wrong for several reasons. First, the website that the Examiner relies on is run by a group of individuals who are far less qualified than any of the declarants. In particular, none of the six individuals that are part of the "Biology Online Team" are doctors - three are still undergraduates, two have bachelor's degrees and one of them is currently a post-doc fellow. Anyone can submit any definition they want to the website where this team of "experts" will review the submission. Second, the Examiner then selects one of three different definitions from Biology Online to argue that the natal cleft and the perianal area are the same, and that the Examiner has a better anatomical understanding of the rectal area than a doctor of proctology who has been practicing in medicine since 1970 (see, e.g., Doctor Freed's Declaration, Appendix D, paragraph 3).

Appellant respectfully submits that a person such as Doctor Freed is more knowledgeable about this area of the human anatomy than the Examiner, and that Doctor Freed's expert knowledge should be deferred to. However, as a further argument, appellant also notes that the "perianal area" can be defined as "the area of soft tissue . . . between the vagina and

the anus in women and between the scrotum and the anus in men" (<http://www.definition-of.com/perianal+area>, accessed May 27, 2010). Thus, according to this definition, the perianal area which applicant's claimed invention addresses relates more to the frontal part of a person's anatomy (e.g., "between the vagina and anus"). In contrast, according to the definition provided by the Examiner, the natal cleft relates more to the back part of a person's anatomy that ends just before the area that applicant's invention addresses (as set forth by the Examiner, the natal cleft runs FROM part of the spine (i.e., the sacrum) TO the perium). Thus, these definitions further support Doctor Freed's declaration that the natal cleft and the perianal area are different areas of anatomy, and that therefore Rosenberg and the claimed invention operate on different parts of a person's body and have a different purpose.

Accordingly, for at least the foregoing reasons, appellant respectfully submits that the Examiner's arguments against Doctor Freed's, Doctor Curet's, and Doctor Steinhagen's declarations that Rosenberg and appellant's claimed inventions have different purposes and operate on different anatomical areas are improper and insufficient. As such, these declarations were improperly dismissed without being given proper consideration.

DECLARATIONS ON UNIQUE STRUCTURE & COMFORT

One beneficial feature of appellant's claimed invention is that it can be worn with comfort. For example, despite the presence of a painful hemorrhoid and having a device strapped to sensitive areas, a wearer of appellant's claimed invention can "freely sit, stand, walk, and otherwise engage in

"routine, daily activities" and "can move freely without any uncomfortable pulling of the skin or muscles and without causing any other discomfort" (see, Suárez's Declaration, Appendix G, paragraph 7; see also, e.g., Curet's Declaration, Appendix E, paragraph 4; and Steinhagen's declaration, Appendix F, paragraph 7). This is a unique result since generally, when a patient's buttocks are being stretched apart and held separated, a patient cannot walk, sit, or move without discomfort and irritation.

One reason appellant's claimed invention can allow for such comfort while still providing the separating action is because of its unique, claimed, "crescent shaped" form. For example, as described in more detail by Doctor Steinhagen, the crescent shape allows the patient's buttocks to be lifted "at a very specific angle that follows the anatomy of the patient's body" (see, Steinhagen's declaration, Appendix F, paragraph 7). This specific angle not only allows "the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects," but it also supports the muscle in a manner that "does not hinder movement of a patient's body" (see, Steinhagen's declaration, Appendix F, paragraph 7). Steinhagen then goes on to note that "Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention" (see, Steinhagen's declaration, Appendix F, paragraph 7).

Accordingly, as evidenced by Steinhagen's declaration, the unique shape and structure of appellant's claimed invention provides benefits that cannot be duplicated by Rosenberg's simple, straight strapping. The Examiner expressly admits that Rosenberg and applicant's claimed invention are structurally

different because Rosenberg does not show appellant's unique feature of a crescent-shaped structure (see, e.g., Final Office Action, page 12). However, the Examiner then dismisses the declarations of the unique shape of appellant's claimed invention and the benefits resulting therefrom, by arguing that "a regular piece of tape, such as used by Rosenberg" could allow "a patient to walk, sit, sleep, or otherwise continue their daily life without discomfort" (see, e.g., Final Office Action, page 8). The Examiner then reasons that Rosenberg is "similar to a belt, which is well known in the art to allow a wearer to perform daily activities normally and in comfort" (see, e.g., Final Office Action, page 8). Appellant respectfully disagrees and submits that the Examiner's reasoning is improper and fails to provide a prima facie case of obviousness.

As an illustration, if one were to merely use a regular piece of tape to stretch one's buttocks apart and secure them in place, one could imagine that it would be extremely uncomfortable to attempt to walk and sit while one's buttocks are distended in such a fashion. Even more so could one imagine the discomfort that would result if one attempted to use a belt to strap one's buttocks apart. Accordingly, appellant respectfully submits that, by reasoning that a belt or tape could be used to comfortably hold one's buttocks apart, that the Examiner has not given proper consideration to Doctor Steinhagen's declaration or to the Examiner's own arguments. Therefore, Doctor Steinhagen's declaration with regards to the unique shape and structure of appellant's claimed invention was improperly dismissed.

As a further argument against the unique shape and structure of the claimed invention, the Examiner argues that "it

is not clear, that the device of Rosenberg, properly applied by one of ordinary skill in the art of hemorrhoid treatment would not produce the same results [as appellant's claimed invention]" (see, Final Office Action, page 7). The Examiner's statement, on its face, is purely speculative. In fact, in the more than thirty years since Rosenberg was published, there are no known instances where anyone has done as the Examiner suggests, even though the problems related to hemorrhoids disability, pain, and healing continues to this very day. Moreover, appellant has provided multiple declarations from those skilled in the art who have explicitly stated that Rosenberg does not produce the same results and comfort as the claimed invention (see, e.g., Steinhagen's declaration, Appendix F, paragraph 7).

As briefly alluded to above, appellant notes that the Rosenberg reference was published in 1977. Regardless, despite the fact that the Rosenberg reference has been available for over 30 years, applicant is unaware that even a single doctor, during these 30 years, has sought to use or even modify the Rosenberg reference to produce the results of appellant's claimed invention. Rather, as attested to by Doctor Steinhagen, to his knowledge no one has ever developed a product similar to appellant's claimed invention (see, e.g., Steinhagen's Declaration, Appendix F, paragraph 11). Appellant thus respectfully submits that this is further evidence of non-obviousness, and that Rosenberg could not be applied to produce the same results as the claimed invention since, if Rosenberg could be applied to produce the same results and comfort, then at least one doctor in the past 30 years would have done so.

As another argument in response to the Examiner's contention that Rosenberg could allegedly be applied to produce

the same results and comfort as the claimed invention, appellant notes that Rosenberg is designed to treat a different disease. For example, Rosenberg is designed to treat pilonidal disease, whereas appellant's claimed invention is intended be used to treat hemorrhoids (see, e.g., Rosenberg, Column 1, lines 1-3; Freed's Declaration, Appendix D, paragraph 7; and Curet's Declaration, Appendix E, paragraph 8). In the area of medicine, one cannot generally swap treatment for one disease with the treatment for a different disease. Rather, each disease is generally treated specifically for its own causes and symptoms. Accordingly, appellant respectfully submits that a device for treating pilonidal disease, such as the Rosenberg device, cannot simply be swapped with the claimed invention to produce the same results as the claimed invention.

Accordingly, for at least the foregoing reasons, appellant respectfully submits that declarations regarding the unique shape and structure of appellant's claimed invention, and the unique comfort and benefits resulting therefrom, were not given proper consideration. As such, these declarations were improperly dismissed.

CONCLUSION REGARDING THE DECLARATIONS

Accordingly, for at least the foregoing reasons, appellant respectfully submits the declarations of Doctor Freed, Doctor Steinhagen, Doctor Curet, and Mrs. Suárez were not given proper consideration. In particular, appellant respectfully submits that these declarations with regards to at least the non-obviousness of the claimed invention, the differences in purpose and application between Rosenberg and the claimed invention, and the unique shape and structure of the claimed

invention and the benefits resulting therefrom were not given proper consideration. These declarations were therefore improperly dismissed.

B. Appellant's Response to the 103(a) Rejection of claims 13-15, 19, 21, 27, 33-36, and 38-44

The Examiner has finally rejected claims 13-15, 19, 21, 27, 33-36, and 38-44 under 35 U.S.C. § 1.103(a) as allegedly being unpatentable over Rosenberg.

CLAIMS 13 AND 40

Appellant's invention, as defined by independent claims 13 and 40, is directed to a strip that is operable to separate swollen tissue from non-swollen tissue. For example, the swollen tissue may be caused by a hemorrhoids ailment (see, e.g., appellant's specification, page 9, lines 12-15 and claim 40). The strip is "crescent shaped" and is either "substantially planar" (claim 13) or "substantially contained within a single plane" (claim 40). In other words, if appellant's claimed invention were laid down on a surface, it could lie flat against this surface and appear crescent shaped from a top view (See, e.g., appellant's FIG. 3, tape 30). The strip has a length that is at least twice as long as its width. An adhesive is applied to the strip such that the strip is operable to be applied to a person's body in a manner that separates the swollen tissue from the non-swollen tissue when applied.

Nowhere does Rosenberg show or suggest appellant's claimed invention. Rosenberg is directed to an "adhesive

"strapping" used for treating a pilonidal wound (see, Rosenberg, page 291, line 6). This adhesive strapping is only described by a single picture and a single passage of Rosenberg. The picture shows a straight strapping (see, Rosenberg, FIG. 1). The passage reads:

a patient was then asked to strap his buttocks in a reverse direction, that is, wide adhesive strapping was utilized on either side of the wound, stretching outward and crossing on the abdomen in the front (Rosenberg, page 291, lines 4-8)

Apart from this citation and this picture, Rosenberg does not describe the shape or structure of its adhesive strapping. As such, nowhere does Rosenberg show or suggest the unique shape and structure of appellant's claimed invention, such as a strip of material that is "crescent shaped," as required by appellant's independent claims 13 and 33. In fact, the Examiner directly concedes that Rosenberg fails to show a crescent shape (see, e.g., Final Office Action, page 12). Moreover, as evidenced by the submitted declarations, this unique shape and structure, which is not shown by Rosenberg, can provide critical benefits such as enhanced healing effects and allowing a patient to freely walk, stand, and move without experiencing discomfort (see, e.g., Steinhagen's Declaration, Appendix F, paragraph 7; Suárez's Declaration, Appendix G, paragraph 7; and Curet's Declaration, Appendix E, paragraph 4).

The Examiner then argued, however, that even though Rosenberg doesn't show a crescent shape (an express admission by the Examiner), this crescent shape is obvious and "it is unclear to the Examiner why any modification of Rosenberg to allow it to act on hemorrhoidal tissues would be unobvious to one of

ordinary skill in the art" (See, Final Office Action, page 13). The Examiner does not provide any basis for making the suggested structural change to Rosenberg, but instead admits a lack of knowledge in this technical area (i.e., "it is unclear to the Examiner . . . ") which the submitted declarations specifically address. The Examiner admits that "one of ordinary skill in the art is one who normally treats hemorrhoids, e.g., a proctologist or other surgeon" and that such a person requires training of "not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a proctologist" (see, Final Office Action, page 13), which qualification is met by each of the three doctors that submitted declarations in this case. The Examiner then finishes by stating that "given this high level of skill . . . it strains the bounds of credulity to assert that an individual with such a high level of skill would be unable to envision the use of a device as taught by Rosenberg to treat hemorrhoids" (see, Final Office Action, page 13).

However, in direct contrast to the Examiner's contention above, the appellant has provided affidavits from not just one individual, but from three diverse individuals who have achieved this "high level of skill," and all of whom have declared that appellant's claimed invention would not be obvious in view of Rosenberg. Yet, as described above in Heading A of the arguments section of this Appeal Brief, the Examiner simply and improperly dismissed the declarations of each of these three expert individuals.

Moreover, as further evidence of non-obviousness of the claimed invention, appellant notes that people have suffered from hemorrhoids since the beginning of humanity, and that

hemorrhoids is not a trivial malady. Rather, at times hemorrhoids can be severe enough to require invasive surgery and to force patients to stay home and prevent them from working (*see, e.g.*, Suárez's Declaration, Appendix G, paragraphs 3 and 8). As such, there has been a long felt need for a way to effectively treat hemorrhoids without requiring surgery or other invasive and costly techniques. The Rosenberg reference was published in 1977. However, despite the fact that the Rosenberg reference has been available for over 30 years, applicant is not aware of even one doctor during these 30 years that has sought to modify the Rosenberg reference to make the appellant's claimed invention. Appellant's claimed invention then provided a remedy to this long-felt need, where this remedy can not only quickly and effectively heal even the most severe hemorrhoids, but is non-costly, convenient, and can be worn with comfort and without disrupting an individual's everyday life (*see, e.g.*, Suárez's Declaration, Appendix G, paragraphs 1-3 and 5-9; Steinhagen's declaration, Appendix F, paragraphs 7 and 10; Curet's Declaration, Appendix E, paragraph 4; and Appellant's specification, page 8, lines 4-8). This long felt need, that had not been addressed until appellant's claimed invention was created, is thus further proof that the claimed invention is not obvious in view of Rosenberg.

Moreover, appellant respectfully submits that the unique shape and structure of the claimed invention, and the benefits resulting therefrom, are further evidence of the non-obviousness of the claimed invention. For example, as attested to by the declarants and admitted to by the Examiner, the unique shape and structure of the claimed invention can allow a patient to freely sit, stand, walk, and move around without discomfort,

despite the separating action of the buttocks caused by the worn device (see, e.g., Steinhagen's Declaration, Appendix F, paragraph 7; Suárez's Declaration, Appendix G, paragraph 7; and Curet's Declaration, Appendix E, paragraph 4). Moreover, "Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention" (see, Steinhagen's declaration, Appendix F, paragraph 7). Appellant thus respectfully submits that these qualities are further proof that the claimed invention is not obvious in view of Rosenberg.

The Examiner, however, argued in the Final Office Action that the mentioning of a "specific angle" in Steinhagen's declaration means the unique shape and structure of the claimed invention does not show non-obviousness (See, e.g., Final Office Action, page 14). This section of Steinhagen's declaration states that "the claimed invention can operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient's body" (See, Steinhagen's Declaration, paragraph 7). The Examiner then argued that, since appellant's specification does not mention the specific angle, "this must be knowledge which is within the scope of one of ordinary skill in the art [and] would have been obvious" (See, Final Office Action, page 14). Appellant respectfully disagrees.

Appellant notes that, although the "specific angle" is not mentioned in appellant's specification, the "crescent shape" is disclosed in the originally filed application (see, e.g., specification, page 13, lines 27-29 and FIG. 3, tape 30). Various declarations were then submitted as evidence of the way in which this "crescent shape" allows the claimed invention to

uniquely operate, for example, by lifting the inflamed tissue at a specific angle (*see, e.g.*, Steinhagen's declaration, Appendix F, paragraph 7). As such, the mentioning of the specific angle in Steinhagen's declaration is the doctor's expert observation on the manner in which the claimed invention operates. There is no correlation between the absence of this term in the specification, and a conclusion that this term must therefore have been within the scope of one of ordinary skill in the art at the time the application was filed. Moreover, the crescent shape, and not the specific angle, is the feature that is claimed by independent claims 13 and 40. Accordingly, the issue of the obviousness of the specific angle is not related to the obviousness of claims 13 and 40. Accordingly, for at least these foregoing reasons, appellant respectfully submits that the Examiner's arguments with regards to the specific angle are insufficient to show the claimed invention would be obvious in view of Rosenberg.

Additional evidence of the non-obviousness of the claimed invention is that Rosenberg is designed for application to a different part of the body and for treating a different disease than the claimed invention (*see, e.g.*, Freed's Declaration, Appendix D, paragraph 7; Curet's Declaration, Appendix E, paragraph 8; and Steinhagen's Declaration, Appendix F, paragraph 6). For example, Rosenberg operates on "the presacral skin and subcutaneous tissue of the buttocks to eliminate the natal cleft" while appellant's claimed invention operates "in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue" (*see, Freed's Declaration, Appendix D, paragraph 7*). Also, Rosenberg is designed to treat pilonidal disease, whereas

appellant's claimed invention can be used to treat hemorrhoids (*see, e.g.*, Freed's Declaration, Appendix D, paragraph 7; Curet's Declaration, Appendix E, paragraph 8; and Rosenberg, Col. 1, lines 1-3). Appellant thus respectfully submits that it would not have been obvious to one skilled in the art to modify Rosenberg to produce a device that operates on a wholly different disease and on a wholly different part of the anatomy, such as the claimed invention does. This is, therefore, further proof that the claimed invention is not obvious in view of Rosenberg.

Accordingly, for at least the foregoing reasons, appellant respectfully submits that Rosenberg does not show appellant's independent claims 13 and 40, nor would the claimed invention be obvious in view of Rosenberg. Appellant thus respectfully requests that the 35 U.S.C. § 1.103(a) rejection of claim 33, and any claims depending therefrom, including claims 34-39, should be overturned.

CLAIM 33

Appellant's invention, as defined by independent claim 33, is directed to a strip of material that is operable to separate swollen tissue from non-swollen tissue. The strip is "crescent shaped" and is "substantially planar." The strip has a length that is at least twice as long as its width. The strip also includes a tab that is "located on at least one of the first end and the second end" of the strip. An adhesive is applied to the strip such that the strip is operable to be applied to a person's body in a manner that separates the swollen tissue from the non-swollen tissue when applied.

Rosenberg, as admitted by the Examiner, fails to show or suggest appellant's claimed invention, as defined by independent claim 33. For example, as described above with regards to independent claims 13 and 40, Rosenberg fails to show or suggest the unique shape and structure of appellant's claimed invention, such as a strip of material that is "crescent shaped."

Moreover, in addition to failing to show or suggest a crescent shape, Rosenberg also fails to show or suggest a "tab . . . located on at least one of the first end and the second end" as required by appellant's independent claim 33. The Examiner never provides an argument in the Final Office Action as to how the cited art shows or suggests this feature of appellant's claimed invention. Moreover, appellant finds no disclosure of such a tab anywhere in Rosenberg.

For at least the foregoing reasons, appellant respectfully submits that Rosenberg fails to show or suggest appellant's independent claim 33. Appellant thus respectfully requests that the 35 U.S.C. § 1.103(a) rejection of claim 33, and any claims depending therefrom, including claims 34-39, should be overturned.

C. Appellant's Response to the 35 U.S.C.
§ 112, first paragraph Rejection of
claims 13-15, 19, 21, 27, 33-36, and 38-44

The Examiner has finally rejected claims 13-15, 19, 21, 27, 33-36, and 38-44 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner has alleged that the "claims contain subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the length is at least twice or at least three times the width" (see, Final Office Action, page 15). Appellant respectfully traverses this rejection.

Appellant's originally-filed FIG. 3 shows tape 30. In FIG. 3, tape 30 is illustrated as having a length that is at least twice or at least three times as long as its width. Accordingly, the originally-filed application teaches that the length of tape 30 can be at least twice or at least three times the width. Thus, at the time the application was filed, the inventor had possession of this claimed feature.

For at least the foregoing reason, appellant respectfully submits that claims 13-15, 19, 21, 27, 33-36, and 38-44 comply with 35 U.S.C. § 112, first paragraph. Appellant therefore respectfully requests that this rejection of the claims be overturned.

D. Appellant's Response to the 35 U.S.C. § 132(a)
Objection to the Amendment Filed on November 12, 2009

The Examiner objected to the amendment filed on November 12, 2009 under 35 U.S.C. § 132(a) as allegedly introducing new matter (see, Final Office Action, page 15). In particular, the Examiner argued that the new material includes the amendment to show rubber separation knob 38 (i.e., FIG. 3) and the amendment to state the length is at least twice or at

least three times the width (i.e., claims 13, 14, 33, 40, and 41).

THE RUBBER SEPARATION KNOBS

On page 2 of the Non-Final Office Action dated May 13, 2009, the Examiner objected to the figures under 37 C.F.R. § 1.83(a) as failing to show the claimed element, "rubber separation knobs." In response, appellant filed an amended FIG. 3 on November 12, 2009 in which the element, rubber separation knob 38, had been added to the figure. This amendment introduced no new matter and was fully supported by the originally filed application. For example, appellant's originally-filed specification describes that "belt portions 18 and 20 [of garment 10] may also include frictional members (not shown), such as small rubber knobs that further enhance the separation action of the belts" (appellant's specification, page 12, lines 3-6). The originally-filed specification then goes on to describe that "tape 30 may also include a series of attachment members (not shown) at the end . . . such as the rubber knobs described above with respect to garment 10" (appellant's specification, page 14, lines 24-27). As another example, originally-filed claims 16, 18, and 20 read that the apparatus can include "a plurality of frictional members that enhance said separation." Accordingly, the amendment to FIG. 3 filed on November 12, 2009 did not introduce new matter and was fully supported by the originally-filed application.

However, in the currently-pending Final Office Action, the Examiner argued that the amendment to FIG. 3 does introduce new matter since "the number, location, and size of the rubber separation knobs, as well as the relative location of the knobs

with respect to each other in the newly submitted Figure" is allegedly new material (See, Final Office Action, page 15). Appellant respectfully traverses this objection.

As shown above, the subject matter of a rubber separation knob on tape 30 is fully supported by the originally-filed application. The Examiner himself directly conceded that the originally-filed specification discloses such rubber separation knobs (see, e.g., Final Office Action, page 12). Per the Examiner's request, FIG. 3 has been amended to show a rubber separation knob 38. The appellant has not labeled on FIG. 3 nor tried to claim a specific "number, location, and size of the rubber separation knobs [or] relative location of the knobs with respect to each other." Appellant thus respectfully submits that amended FIG. 3 complies with 37 C.F.R. § 1.83(a) and introduces no new matter. Appellant therefore requests that this objection be overturned.

THE LENGTH OF THE CLAIMED INVENTION

The Examiner objected to claims 13, 14, 33, 40, and 41 under 35 U.S.C. § 132(a) as allegedly introducing the new matter of a strip with a length that is at least twice as long as the width (claims 13, 14, 33, and 40) and a length-wise edge that is at least 3 times as long each width-wise edge (claim 41). Appellant respectfully traverses this objection.

Appellant's originally-filed FIG. 3 shows tape 30. In FIG. 3, tape 30 is illustrated as having a length that is at least twice or at least three times as long as its width. Accordingly, the originally-filed disclosure teaches that the length of tape 30 (e.g., or the length-wise edge) can be at least twice or at least three times the width (e.g., or the

width-wise edge). Thus, this feature was disclosed by applicant's originally-filed application.

For at least the foregoing reason, appellant respectfully submits that claims 13, 14, 33, 40, and 41 comply with 35 U.S.C. § 132(a) and introduce no new matter. Appellant therefore respectfully request that the objection to these claims under 35 U.S.C. § 132(a) be overturned.

E. Conclusion

For at least the reasons set forth above, appellant respectfully submits that Rosenberg does not show or suggest any of appellant's claims 13-15, 19, 21, 27, 33-36, and 38-44, that these claims comply with 35 U.S.C. § 112, first paragraph, and that the amendment filed on November 12, 2009 does not introduce new matter. The Final Office Action's objections and rejections should therefore be reversed.

Respectfully submitted,

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CLAIMS APPENDIX A
CLAIMS ON APPEAL

13. Apparatus for relieving discomfort caused by swollen tissue ailments comprising:

a strip of material having first and second ends, wherein:

said strip of material is substantially planar,

said strip of material is crescent shaped,

said strip of material includes a length and a width, wherein the length is at least twice as long as the width,

said strip of material having one side that includes an adhesive applied at least to said first and second ends, and

said strip and said adhesive are operable to be applied to a person's body and to separate said swollen tissue from non-swollen tissue when applied.

14. The apparatus of claim 13, further comprising:

a second strip of material having third and fourth ends, wherein said second strip of material is substantially planar, is crescent shaped, and includes a length and a width, wherein the length is at least twice as long as the width; and

said second strip of material having a side that includes said adhesive applied at least to said third and fourth ends, said second strip and said adhesive, when applied to said

person's body, acting to separate said swollen tissue from said non-swollen tissue.

15. The apparatus of claim 14, wherein said adhesive is absent from a portion of said second strip of material between said third and fourth ends.

19. The apparatus of claim 13, wherein said adhesive is absent from a portion of said strip of material between said first and second ends.

21. The apparatus of claim 13, further comprising:
a protective barrier covering at least said adhesive such that, when said protective barrier is removed and said strip of material is applied to said person's body, said strip of material separates said person's buttocks to relieve discomfort cause by hemorrhoids.

27. The apparatus of claim 13, wherein said length comprises a particular size such that said first and second ends are separated by a distance sufficient for said first and second ends to be respectively applied to said person's buttock and hip simultaneously, wherein said buttock and said hip are on the same side of said person's body.

33. An apparatus for relieving discomfort caused by swollen tissue ailments, the apparatus comprising:

a strip of material that is substantially planar and is crescent shaped, the strip of material comprising:
a first end;

a second end;
 a width;
 a length, wherein the length is at least twice as long as the width;
 an adhesive applied to a first side of the strip of material; and
 a tab, wherein the tab is located on at least one of the first end and the second end; and
 wherein the strip is operable to:
 be applied to a person's body; and
 separate swollen tissue from non-swollen tissue when applied.

34. The apparatus of claim 33, wherein the adhesive is absent from a portion of the first side of the strip of material between the first end and the second end.

35. The apparatus of claim 33, wherein the adhesive is applied to the entirety of the first side of the strip of material.

36. The apparatus of claim 33, wherein the length comprises a particular size such that the first end and the second end are separated by a distance sufficient for the first end and the second end to:

 be applied, respectively, to the person's buttock and to the person's hip at the same time, wherein the buttock and the hip are on the same side of the person's body; and
 separate the swollen tissue from non-swollen tissue when applied.

38. The apparatus of claim 33, wherein the strip of material further comprises:

one or more rubber separation knobs, wherein the one or more rubber separation knobs are located on at least one of the first end and the second end.

39. The apparatus of claim 33, further comprising:

a second strip of material that is substantially planar and is crescent shaped, wherein the second strip of material comprises:

an adhesive applied to one side of the second strip; and

a tab, wherein the tab is located on at least one of the ends of the second strip.

40. An apparatus for relieving discomfort caused by swollen tissue resulting from hemorrhoids, the apparatus comprising:

a first strip comprising:

a top surface and a bottom surface, wherein each surface is flat such that the first strip is substantially contained within a single plane;

two length-wise edges, wherein each length-wise edge is curved such that the shape of the strip is crescent-shaped in form;

two width-wise edges, wherein each length-wise edge is at least 2 times as long as each width-wise edge; and

an adhesive applied to at least a portion of the bottom surface, wherein the adhesive is operable to couple the first strip to a person's body in a manner that separates the swollen tissue from non-swollen tissue.

41. The apparatus of claim 40, length-wise edge is at least 3 times as long as each width-wise edge.

42. The apparatus of claim 40, further comprising: at least one tab extending from an intersection of a length-wise edge and a width-wise edge, wherein the at least one tab is contained within the single plane.

43. The apparatus of claim 40, wherein the adhesive is absent from a middle portion of the bottom surface.

44. The apparatus of claim 40, wherein the bottom surface comprises:
two end portions, wherein each end portion comprises a different width-wise edge, and wherein the adhesive is only applied to the two end portions.

(ix) Evidence Appendix

EVIDENCE APPENDIX B

Copy of Final Office Action
Dated February 22, 2010



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,258	10/28/2003	Rebecca Gomez	REB/001 Div	7051
31013	7590	02/22/2010	EXAMINER	
KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3769	
		NOTIFICATION DATE	DELIVERY MODE	
		02/22/2010	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No. 10/696,258	Applicant(s) GOMEZ, REBECCA
	Examiner david shay	Art Unit 3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on November 12, 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-15,19,21,27,33-36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-15,19,21,27,33-36 and 38-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
 6) Other: _____

Several Declarations have been submitted by applicant. The examiner will now analyze these Declarations.

A Declaration submitted by Maria Suarez, states at paragraph 1 that Declarant was a patient suffering from grade 4 hemorrhoids that had become thrombosed. At paragraph 2, Declarant notes that she had tried various treatments, including suppositories and various topical agents includinh Preparation H and Peranex, to little or no effect. At paragraph 3, Declarant states that her doctor had tried draining the hemorrhoid, but felt that surgery was inevitable. In paragraph 4 Declarant states that she has reviewed the instant application and the claims thereof. At paragraph 5, Declarant states that she suffered from the hemorrhoids for 13 days prior to using the claimed invention. At paragraph 6, Declarant states that after suffering from the previously discussed hemorrhoid, Declarant used the claimed invention in the hopes of avoiding surgery. At paragraph 7, Declarant notes that the claimed device was worn continuously, but allowed free movement without pulling of the skin or any other discomfort. Declarant also notes that she was able to perform her normal daily activities without encumbrance while using the device, including going out in public, as the device did not show through clothing. In paragraph 8, Declarant notes that she was able to return to work immediately, and was able to concentrate and perform well at work due to using the device. Declarant then states, in paragraph 9, that "this was one of the most severe hemorrhoids I had experienced" and noted that the claimed invention allowed her to heal very rapidly and avoid surgery. Declarant's statements are noted, as to the efficacy and convenience of the device.

A second declaration by Sandra L. Curet was also submitted. The examiner will now review this Declaration. Declarant begins by noting her qualifications: she graduated as an MD

from The University of Puerto Rico, School of Medicine and practiced for the last 17 years as an Obstetric and Gynecological physician, a position that enabled her to become very familiar with the ailment of hemorrhoids. In paragraph 3, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 4, Declarant asserts that she is very familiar with the “design and purpose” of the claimed invention, stating the claimed invention “has an ergonomic structure which does not restrict a patient’s movement and is comfortable to wear, thus allowing the patient to continue their daily activities despite the presence of the hemorrhoid or the wearing of the claimed invention”. Declarant goes on to state that the claimed invention operates by separating the inflamed tissue, resulting in quickened healing and reduction of the pain associated with the hemorrhoid and that the invention is easily applied and is user friendly for the patient. At paragraph 5, Declarant states that in her expert opinion, the product (presumably the claimed invention) is very effective in providing pain relief and allowing healing, and that she is eager for the claimed invention to become available commercially, so she may recommend it’s usage to her patients. At paragraph 6, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 7 Declarant states that she has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a “reverse bandaging” technique wherein adhesive strapping is applied to the buttocks and crossed in front of the abdomen. At paragraph 8, Declarant asserts that “the purpose and technology in Rosenberg are different from the claimed invention”, stating that “Rosenberg is designed to work in a different anatomical area than the claimed invention” and that Rosenberg is designed for treating the wound resulting from the removal of a pilonidal cyst, while the instant invention can be used for reducing

inflammation and pain associated with a hemorrhoid. At paragraph 9, Declarant states that “the stated differences between the invention and the prior art “demonstrate the superiority of the claimed invention over Rosenberg”. At paragraph 10, Declarant states that in her opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art. At paragraph 11, Declarant states that with regard to the device of Rosenberg and the instant device, that she finds “no similarities in the purpose, application, and design” of the two devices.

The examiner notes the statements made by Declarant in paragraphs 1-7. Subsequent statements, however, require closer scrutiny. The statement that “the purpose and technology in Rosenberg are different from the claimed invention”, is somewhat puzzling. It is quite clear from the Rosenberg publication that “all factors causing friction in daily work habits prevented epithelialization” (see Rosenberg, page 290, column 1, second paragraph, third sentence) thus clearly Rosenberg identified friction as an impediment to the proper healing of the wound. Rosenberg also identified the solution to this problem – separation of the gluteal cleft (see Rosenberg, page 290, the paragraph beginning at column 2, second sentence). When faced with recalcitrant cases, which were determined to be resistant to treatment due only to “mechanical factors” (see the sentence bridging pages 290 and 291 of Rosenberg), Rosenberg determined to use adhesive strapping “on either side of the wound” wherein the “net effect was to flatten out the wound and remove most of the angle of the interglutal clefts” (see page 291, column 1, first full paragraph). Clearly Rosenberg understood that the frictional engagement of the buttocks with the injured tissue was a barrier to proper healing, and that the solution was to tape the buttocks out of the way. Further, while Declarant’s statement that “Rosenberg is designed to

work in a different anatomical area than the claimed invention" may be true, it is also true that the "different anatomical area" is only inches from the area treated by applicant, and that the area still involves the buttocks. Similarly, the manner in which the "superiority" of the instant device over Rosenberg manifests itself is not clear, as it appears no comparative testing was done to determine the relative efficaciousness of the two devices. Thus while the assertion of superiority in paragraph 9 is noted, it remains only an assertion. Declarant's opinion that the differences between the two devices would not be obvious, asserted in paragraph 10 are also noted. However, the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find "no similarities in the purpose, application, and design" of the two devices, the examiner has found many: both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities.

A third declaration by Randolph M. Steinhagen was also submitted. The examiner will now review this Declaration. Declarant begins by noting his qualifications: he is the Chief of the Division of Colon and Rectal surgery at Mount Sinai Medical Center and is the Professor of Surgery in the Mount Sinai School of Medicine. In paragraph 2, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 3, Declarant asserts that he worked in a clinical trial of the claimed invention, the results of which indicated

that the claimed invention “was generally a success and preferred by the subjects of the trial”. At paragraph 4, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 5 Declarant states that he has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a “strapping” technique wherein adhesive strapping is applied to the buttocks and crossed in front of the abdomen. At paragraph 6, Declarant asserts that the device of Rosenberg is applied to a different part of the body than the claimed invention and is for a different purpose, noting that the claimed invention “includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids”, further noting that this obviates the need for surgery. At paragraph 7, Declarant states that “the claimed invention has a unique shape and structure not shown by Rosenberg” and continuing, states that the invention “can operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient’s body”. Declarant also asserts that this “particular lifting that is provided by the unique shape and structure of the claimed invention can allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects of the inflamed tissue” and continues, stating that “the specific angle at which the claimed invention lifts the inflamed tissue and does not hinder movement of a patient’s body” which allows “a patient to walk, sit sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application of the claimed invention. Concluding, Declarant asserts “Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention”. At paragraph 8, Declarant stated differences between the invention and the prior art “demonstrate the superiority of the claimed invention

over Rosenberg". At paragraph 9, Declarant states that in his opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art at the time the application was filed. At paragraph 10, Declarant states that in his expert opinion many people could benefit from the claimed invention, which provides the benefits such as enhanced healing and mitigating the need for surgery. At paragraph 11, Declarant that Rosenberg does not show the claimed invention, nor to Declarant's knowledge, is any produce similar to the claimed invention currently commercially available and after comparing the device of Rosenberg with the instant device, that he concludes "that any supposed similarities between Rosenberg and the claimed invention are minimal at best and negligible".

The examiner notes the statements made by Declarant in paragraphs 1-5 and 10. Subsequent statements, however, require closer scrutiny. Declarant's statement in paragraph 6, that the device of Rosenberg is applied to a different part of the body than the claimed invention and is for a different purpose, noting that the claimed invention "includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids" may be true, it is also true that the "different part of the body" is only inches from the body part treated by applicant, and that the area still involves the buttocks. Further, it seems apparent that the device of Rosenberg, applied a few inches farther down the buttocks, would have the same effect as the device of applicant. The statement in paragraph 7 that "the claimed invention has a unique shape and structure not shown by Rosenberg" is noted, however, it is not clear, that the device of Rosenberg, properly applied by one of ordinary skill in the art of hemorrhoid treatment would not produce the same results, and thus would be able to

“operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient’s body” and produce the “particular lifting” since this could be produced by separating the gluteal cleft so as to reduce or prevent mechanical friction (as taught to be desirable by Rosenberg, as set forth above) on the hemorrhoid. This would (via the shrinkage of the tissue due to the removal of the irritation caused by the friction from the buttocks during normal motion) “allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects of the inflamed tissue”. Further, there is no evidence that the device of Rosenberg “does not hinder movement of a patient’s body” which allows “a patient to walk, sit sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application” thereof. Indeed, the configuration of the device of Rosenberg is similar to a belt, which is well known in the art to allow a wearer to perform daily activities normally and in comfort. As to Declarant’s concluding assertion, which states that “Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention”, the examiner finds no correlation between the premise and the conclusion since, for example, a regular piece of tape, such as used by Rosenberg, could be affixed to the patient in a curvilinear manner (albeit with some portions of the tape not contacting the skin on the inner portion of the curve) and perform in the same way. Thus, the manner in which the “superiority” of the instant device over Rosenberg manifests itself is not clear, as it appears no comparative testing was done to determine the relative efficaciousness of the two devices. Thus while the assertion of superiority in paragraph 8 is noted, it remains only an assertion. Declarant’s opinion that the differences between the two devices would not be obvious, asserted in paragraph 9 are also noted. However,

the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find that "Rosenberg does not show the claimed invention", the examiner notes that both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities, the absence of similar products in the marketplace does not speak to the matter of non-obviousness, as this may be due to other factors, such as the ability of available surgical tape to perform the same function.

A fourth declaration by Jeffrey Stephen Freed was also submitted. The examiner will now review this Declaration. Declarant begins by noting his qualifications: he graduated cum laude from the State University of New York School of Medicine, he currently specializes in proctology and in general surgery, and has been an associate attending at Mount Sinai Medical Center since 1992; Section Chief of Surgery at Bronx Veterans Hospital since 1979; attending at Beth Israel Hospital since 1982; attending at Lenox Hill Hospital since 1987; and is the Chief of the Division of Colon and Rectal surgery at Mount Sinai Medical Center and has been an associate clinical professor at Mount Sinai Medical Center since 1992. In paragraph 4, Declarant avers familiarity with the claimed invention and having reviewed the application and claims. In paragraph 5, Declarant asserts that he worked in a clinical trial of the claimed invention, the results of which indicated that the claimed invention "was generally a success and preferred by

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the subjects of the trial". At paragraph 6, Declarant asserts a familiarity with the reference to Rosenberg applied to the claims. At paragraph 7 Declarant states that he has compared the technology described in the claimed invention to that of Rosenberg, noting that Rosenberg describes a treatment for pilonidal cysts, as opposed to hemorrhoids, noting that Rosenberg teaches strapping the patient's buttocks with adhesive strapping crossing in the front of the abdomen. Continuing, Declarant asserts that "a marked difference between Rosenberg and the claimed invention is that the strapping of Rosenberg operates by pulling on tissue to change the anatomic nature of the presacral skin and subcutaneous tissue of the buttocks to eliminate the natal cleft" Continuing, Declarant asserts that the structure of the instant invention allows it to operate in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue". At paragraph 8, Declarant states that the differences between the invention and the prior art "show the superiority of the claimed invention" since the claimed invention can provide enhanced hemorrhoidal healing. At paragraph 9, Declarant states that in his opinion, the superiority of the instant device, and the differences between the instant device and the prior art would not have been obvious to one of ordinary skill in the art at the time the application was filed, and that Rosenberg does not show the claimed invention.

The examiner notes the statements made by Declarant in paragraphs 1-6. Subsequent statements, however, require closer scrutiny. Declarant's statement in paragraph 7, that the device of Rosenberg "operates to change the anatomic nature of the presacral skin and subcutaneous nature of the buttocks to eliminate the natal cleft." It is noted, however, as the natal cleft is "The groove or crack between the buttocks that runs from below the sacrum to the perineum; or the groove in which the anus is situated" (from <http://www.biology-onlinc.org>), it is

clear that the instant device and that of Rosenberg are both intended to operate on the same bodily structure. Further, given that each device operates to pull the buttocks apart (to change the anatomic nature fo the buttocks, and the subcutaneous tissue thereof), so as to increase the angle of the cleft and that this is done to reduce or eliminate "all factors causing friction" (see Rosenberg, page 290, column 1, second paragraph, second sentence), it is unclear what, if any "marked difference" there is between the operation of the two devices. Thus while the assertion of superiority in paragraph 8 is noted, it remains only an assertion. Declarant's opinion that the differences between the two devices would not be obvious, asserted in paragraph 9 are also noted. However, the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find that "Rosenberg does not show the claimed invention", the examiner notes that both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities, and thus the devices are quite similar in their structure and operation.

With regard to the election by original presentation, applicant asserts that the examiner has failed to provide "reasonable examples that recite material differences" to show that claims 28-32 are distinct. In order to make the record more complete, the examiner presents herein an explanation of the material differences between the apparatus and method of use. The details of

the application of the device to the body recited in the apparatus claims merely constitute statements of intended use, and do not add anything to the structure of the device already recited. As such, the device could be employed in a rolled up configuration and inserted into the gluetial cleft of the user above and below the hemorrhoidal tissue, the adhesive serving to secure the rolled up device in the rolled up configuration and/or to secure the device to the user's tissue. Therefore the method of use of the device recited in claims 28-32 is distinct from the claimed apparatus, and the restriction is proper.

The examiner has reviewed applicant's remarks regarding the holding of new matter in the previous office action. It is clear from the originally filed disclosure that the rubber separation knobs were disclosed in the text of the originally filed disclosure, thus this objection, with respect to the specification, has been withdrawn.

With regard to the rejection under 35 U.S.C. 112, second paragraph, applicant's amendments have obviated this rejection.

Regarding the prior art, applicant first addresses the Rosenberg publication, noting that there is no disclosure in Rosenberg that the device disclosed therein is "crescent shaped" as now claimed. However, the examiner notes that this shape is not critical, as set forth at page 13, lines 27-29 "Tape 30 may be made in any shape, such as the crescent-like shape shown in Figure 3, or other suitable shapes." And while Rosenberg does not show a crescent shape, this does not eliminate Rosenberg as a reference under 35 U.S.C. 103(a). Pointing to the Declarations filed under 37 C.F.R. 1.132, applicant asserts that the instant device can provide a wide range of benefits for the user, as denoted in the Declarations, and the differences between the instant device and that of Rosenberg.

As set forth above, the assertions of many benefits and differences in the structure and method of application of the instant device and that of Rosenberg are noted, however, it is unclear to the examiner why any modification of Rosenberg to allow it to act on hemorrhoidal tissue would be unobvious to one of ordinary skill in the art. To summarize, as the instant invention is directed to the treatment of hemorrhoids, one of ordinary skill in the art is one who would normally treat hemorrhoids, e.g. a proctologist or other surgeon. Given that, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a proctologist or other surgeon. Given this high level of skill, the proposition that one of ordinary skill in the art would not realize that a treatment for the wound generated by the treatment for pilonidal cysts, wherein the buttocks are separated from the wound and maintained in this position by adhesive means, and wherein the reason for this is that healing is prevented by "all factors causing friction in daily work habits prevented epithelialization" (see Rosenberg, page 290, column 1, second paragraph, third sentence), as referenced above, it strains the bounds of credulity to assert that an individual with such a high level of skill would be unable to envision the use of a device as taught by Rosenberg to treat hemorrhoids – a condition which has long been recognized as exacerbated by friction (see the supplied references to Tallent {specifically see column 2, lines 37-40} and McFaul, Sr. {specifically see column 1, lines 7-10}) and wherein the friction arises, at least in part, from the very bodily structure as in the case of pilonidal cysts, i.e. the buttocks. And it is similarly difficult to imagine that such a skilled practitioner would be unable to modify the device of Rosenberg to provide the desired effects of separation of the gluteal cleft such that the

hemorrhoids are not interfered with, especially in view of the fact that the originally filed disclosure specifically states that the device can be configured as a single strip which stretches from hip to hip, across the buttocks, as set forth at page 15, lines 14-19: “the strip may be a single strip that is intended to stretch from one hip, across the buttocks to the other hip (in which case each buttock would be attached), or a single strip that attaches to each buttock and wraps around the front of the affected individual.”

Continuing, applicant argues that (as set forth in the Declarations) that due to “the unique shape and structure, inflamed tissue caused by a hemorrhoid can be lifted at a specific angle that follows the anatomy of the patient’s body”. This argument is interesting, in that there is no mention whatsoever in the originally filed disclosure of lifting tissue “at a specific angle”. As this is nowhere discussed in the originally filed disclosure, this must be knowledge which is within the scope of one of ordinary skill in the art. As such, the knowledge of the desire to so lift the tissue, as well as the “specific angle” which is required would have been obvious to one of ordinary skill in the art.

The remainder of applicant’s arguments consist of reiterating the points made in the Declarations, and as such have already been addressed above with respect thereto. Therefore, the examiner will not burden the record by repeating them here, instead applicant is referred to these arguments as enumerated above.

The rejections based on DeMarco, Diaz, and Valentin have been withdrawn. It is noted that applicant’s supposition that the Valentin reference was intended to be applied under 35 U.S.C. 102(e), rather than 35 U.S.C. 102(c) is correct.

The amendment filed November 12, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the number, location, and size of the rubber separation knobs, as well as the relative location of the knobs with respect to each other in the newly submitted Figure, and that the length is at least twice or at least three times the width.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the length is at least twice or at least three times the width.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg. Rosenberg teaches a device such as claimed except for the crescent shape and the rubber separation knobs. It would have been obvious to the artisan of ordinary skill to configure the device of Rosenberg in a crescent shape, since this is not critical; is well within the scope of one having ordinary skill in the art; provides no unexpected result;

and would allow the device to more closely conform to the body of the user, and to lift the tissue at a particular angle, which is within the knowledge of one of ordinary skill in the art, as set forth above, and to employ rubber separation knobs on the devices of Rosenberg, since such knobs are known to provide better frictional engagement with compliant surfaces to which they are applied, thus producing a device such as claimed.

Applicant's arguments filed November 12, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30

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p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769

Notice of References Cited		Application/Control No.	Applicant(s)/Patent Under Reexamination	
		10/696,258	GOMEZ, REBECCA	
Examiner david shay		Art Unit 3769	Page 1 of 1	

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-3,894,539	07-1975	Tallent, L. Dee	604/57
*	B US-4,932,397	06-1990	McFaul, Sr., Stephen E.	128/887
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
R					
S					
T					

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a))
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i>		Application/Control No.		Applicant(s)/Patent Under Reexamination	
		10696258		GOMEZ, REBECCA	
Examiner		Art Unit			
david shay		3769			

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIM				DATE			
Final	Original	11/27/2007	05/10/2009	02/09/2010			
1	-	-	-				
2	-	-	-				
3	-	-	-				
4	-	-	-				
5	-	-	-				
6	-	-	-				
7	-	-	-				
8	-	-	-				
9	-	-	-				
10	-	-	-				
11	-	-	-				
12	-	-	-				
13	✓	✓	✓				
14	✓	✓	✓				
15	✓	✓	✓				
16	✓	-	-				
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18	✓	-	-				
19	✓	✓	✓				
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28	N	N					
29	N	N					
30	N	N					
31	N	N					
32	N	N					
33	✓	✓					
34	✓	✓					
35	✓	✓					
36	✓	✓					

<i>Index of Claims</i>		Application/Control No.		Applicant(s)/Patent Under Reexamination	
		10696258		GOMEZ, REBECCA	
Examiner		Art Unit			
david shay		3769			

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47	
CLAIM			DATE					
Final	Original		11/27/2007	05/10/2009	02/09/2010			
	37		✓	-				
	38		✓	✓				
	39		✓	✓				
	40			✓				
	41			✓				
	42			✓				
	43			✓				
	44			✓				

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10696258	GOMEZ, REBECCA
Examiner	Art Unit	
david shay	3769	

SEARCHED

Class	Subclass	Date	Examiner
602	60	12/5/2007	JS
602	61	12/5/2007	JS
	Updated	8/16/2008	hmj
	update	5/9/2009	dms
450	81, 86-88	5/10/2009	"
	update	2/8/2010	"

SEARCH NOTES

Search Notes	Date	Examiner
EAST inventor name search	11-27-2007	J.S.
see attached EAST search history	12-5-2007	J.S.
Updated	8/16/2008	hmj

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

EVIDENCE APPENDIX C

Copy of Rosenberg Non-Patent Literature:
"The Dilemma of Pilonidal Disease"; *Diseases of the
Colon and Rectum*: May-June, 1977

Relied upon by the Examiner in the
final rejection of claims 13-15, 19, 21, 27, 33-36,
and 38-44 involved in this appeal

Symposium

The Dilemma of Pilonidal Disease:

Reverse Bandaging for Cure of the Reluctant Pilonidal Wound

IRVING ROSENBERG, M.D.*

DR. HANLEY

Our next speaker is Dr. Irving Rosenberg, who will talk on "Reverse Bandaging for Cure of the Reluctant Pilonidal Wound."

DR. ROSENBERG

Mr. Chairman, Members of the Society, and Guests: In the course of treating pilonidal cyst by open methods, one is impressed with the ease by which some wounds heal and by the difficulty with others. In following the progress of these wounds closely, I was impressed by the fact that the narrowness of the angle between the buttocks and the area known as the intergluteal cleft apparently made a great deal of difference in the healing rate of the inferior end of the pilonidal wound when, in fact, it reached this area. In those cases where the wound extended into the intergluteal cleft, all factors causing friction initially worked to prevent epithelialization unless some strange measures were taken. In those cases in which this difficulty was present, I was forced to rely on some extraordinary means. One trick was to coat the wound with a substance such as Desitin ointment so that in the daily activities, the two sides did not physically touch, but were separated by a barrier of the ointment. This worked in a

moderate number of cases. Women were asked not to wear girdles or corsets and, in a few severe cases, we asked the patient to go to bed for a week and engage in no activity. This was successful in at least two cases.

In another set of circumstances we used Tampax®. This tampon is rather firm, yet absorbent, and when placed in the intergluteal cleft, keeps it separated. This also worked in a moderate number of cases. We were, however, faced with three cases in which, in spite of everything, the wounds failed to heal. The first case was that of a young man, 18 years of age, who was extremely corpulent, weighing approximately 280 pounds, and 5 feet, 8 inches tall. He had an infected pilonidal cyst with multiple openings and a great deal of hair protruding from the ostium. This was removed surgically by open technique and the wound packed off. The healing was relatively uncomplicated and so it became a fist wound, at which time no epithelialization would take place. The surface of the wound was replaced with fibby, pale granulations which were cauterized, and silver nitrate was applied weekly and biweekly, all this to no avail. After approximately 18 months of this treatment, it was decided to take the patient back to the operating room and start from scratch. This was done, and within six months, we had the same result we had the first time. The case was re-evaluated and we

* 6600-C Castor Avenue, Philadelphia, Pennsylvania 19149.

concluded that there was no reason that this wound should not heal other than the mechanical factors involved.

The patient was then asked to strap his buttocks in a reverse direction, that is, wide adhesive strapping was utilized on either side of the wound, stretching outward and crossing on the abdomen in front. The net effect of this was to flatten out the wound and remove most of the angle of the intergluteal clefts.

To my amazement, in two weeks this wound was completely healed and stayed healed.

This method was utilized in another case of a man who was not corpulent, but who had an extreme angle, very acute and very deep. His wound defied complete closure of its inferior end for 18 months. Application of the reverse adhesive tape dressing was successful within three weeks, and the patient has remained well.

In a third case, in a 29-year-old man who had had a previous pilonidal cyst removed and repaired by primary closure by another surgeon, an abscess and fistulization developed. At re-operation, the old surgical wound was converted to an open wound, removing all the cotton suture that had been placed in the depth of the wound. Once again, the typical course was run, where the wound healed relatively promptly, but no epithelialization would take place on its surface. After nine months, it was decided to



Fig. 1. Patient with buttocks strapped in reverse direction.

try the reverse strapping and, to my amazement, this patient's wound was completely healed in 28 days and has remained so ever since.

It is suggested that in those cases of pilonidal wound healing in which the inferior angle does not close, the simple method of reverse strapping may be a great aid in accomplishing a good result. Thank you.

DR. HANLEY

Thank you very much, Dr. Rosenberg.

EVIDENCE APPENDIX D

Copy of the Declaration under 37 C.F.R § 1.132 of
Doctor Jeffrey Stephen Freed, originally filed by appellant on
November 12, 2009

PATENTS
REB-001 Div

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez

Application No. : 10/696,258 Confirmation No. : 7051

Filed : October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS

Art Unit : 3769

Examiner : David M. Shay

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF JEFFREY STEPHEN FREED

Sir:

I, Jeffrey Stephen Freed, hereby declare as follows:

1. That I am a citizen of the United States of America and that I reside in New York City, New York;

2. That I graduated cum laude from the State University of New York, College of Medicine, located in Brooklyn, New York with a Medical Doctor degree in the year 1970;

3. That I have been working in the field of medicine since 1970, and I currently specialize in proctology (the branch

of medicine dealing with the diagnosis and treatment of disorders of the colon, rectum, anus) and in general surgery. I have been an associate attending at Mount Sinai Medical Center since 1992, I have been Section Chief of Surgery at Bronx Veterans Hospital since 1979, I have been attending at Beth Israél Hospital since 1982, and I have been attending at Lenox Hill Hospital since 1987. I have been an associate clinical professor at Mount Sinai Medical Center since 1992;

4. That I am familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I have reviewed the Application and the claims therein which are at issue;

5. That I know of no prior technology that is similar to the claimed invention or that provides relief of hemorrhoidal symptoms in the same manner. The claimed invention describes a unique shape and structure that has the ability to relieve mechanical stress on swollen tissue in the perianal area, thus providing rapid and immediate relief of hemorrhoidal symptoms. This may, for example, allow relief of symptoms without the use of potentially harmful medications, such as cortisone. Moreover, in addition to providing immediate relief of hemorrhoidal discomfort, the claimed invention can provide enhanced healing of hemorrhoids, thus obviating the need for a patient to undergo intrusive and painful procedures such as surgery;

6. That I have reviewed the following Rosenberg reference cited by the Examiner, *The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal*

Wound (hereinafter referred to as "Rosenberg"). It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the above-identified patent application have been rejected by the Examiner based on Rosenberg;

7. That I have compared the technology described by Rosenberg to the claimed invention of the Application. Rosenberg was published in 1977 and describes treating pilonidal disease, which is in contrast to the claimed invention that may be used to treat hemorrhoids. To treat pilonidal disease, Rosenberg describes strapping a patient's buttocks with adhesive strapping crossing the front of the abdomen. A marked difference between Rosenberg and the claimed invention is that the strapping of Rosenberg operates by pulling on tissue to change the anatomic nature of the presacral skin and subcutaneous tissue of the buttocks to eliminate the natal cleft. The structure of the claimed invention, on the other hand, allows the claimed invention to operate in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue, thereby preventing the creation of further hemorrhoidal inflammation and its resultant pain, and allowing the hemorrhoid to experience enhanced healing effects;

8. That the above-mentioned differences between Rosenberg and the claimed invention show the superiority of the claimed invention, in that the claimed invention can, for example, provide enhanced hemorrhoidal healing and symptoms relief not shown by Rosenberg;

9. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been obvious to one skilled in art at the time the Application was filed, and that Rosenberg does not show the claimed invention;

10. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable b y fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

10/14/09

Date

Jeffrey S. Freed

Jeffrey S. Freed

EVIDENCE APPENDIX E

Copy of the Declaration under 37 C.F.R § 1.132 of
Doctor Sandra L. Curet, originally filed by appellant on
November 12, 2009

PATENTS
REB-001 Div

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez

Application No. : 10/696,258 Confirmation No. : 7051

Filed : October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS

Art Unit : 3769

Examiner : David M. Shay

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF SANDRA L. CURET

Sir:

I, Sandra L. Curet, hereby declare as follows:

1. That I graduated from the University of Puerto Rico, School of Medicine, located in San Juan, Puerto Rico with a Medical Doctor degree in 1988;

2. That I have been practicing as an Obstetric and Gynecologist physician for the past 17 years and am very familiar with the ailment of hemorrhoids. Moreover, I am currently a full-time faculty member in the Department of Obstetrics and Gynecology at Lehigh Valley Hospital located in Allentown, Pennsylvania. I am currently the Director of

Ambulatory Services for the Center for Women's Health at Lehigh Valley Hospital located in Allentown, Pennsylvania.

3. That I am very familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I have reviewed the Application and the claims therein which are at issue;

4. That I am very familiar with the structural design and purpose of the claimed invention, and have been following the progress of the claimed invention throughout its development by the inventor, Rebecca Gomez. The claimed invention has an ergonomic structure that does not restrict a patient's movement and is comfortable to wear, thus allowing a patient to continue with their daily activities despite the presence of the hemorrhoid or the wearing of the claimed invention. The claimed invention can operate by separating the inflamed tissue, thus resulting in the quickened healing of the hemorrhoid and the reduction of the hemorrhoid's associated pain. Furthermore, the claimed invention is easily applied and is user-friendly for a patient;

5. That, in my expert opinion, the product is very effective in providing relief of hemorrhoidal pain and in healing hemorrhoids, and thus helps improve and maintain the quality of life in patients. I am eager for the claimed invention to become available on the market and fully intend to recommend the claimed invention for use by my patients when it does become available;

6. That I am familiar with the following Rosenberg reference cited by the Examiner, *The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal Wound* (hereinafter referred to as "Rosenberg"). It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the Application have been rejected by the Examiner based on Rosenberg;

7. That I have reviewed the Rosenberg publication and have compared the technology described therein to the claimed invention of the Application. Rosenberg describes a "reverse bandaging" technique in which an adhesive strapping is strapped to a person's buttocks and crossed in front of the abdomen;

8. That both the description and the purpose of the technology in Rosenberg are different from the claimed invention. As one example, the technology of Rosenberg is designed to work in a different anatomical area than the claimed invention. As another example, the technology of Rosenberg is designed for treating a wound following a pilonidal cyst surgery, whereas the structure of the claimed invention can be used for reducing inflammation and pain associated with hemorrhoids and enhancing the healing of the hemorrhoid. The claimed invention can provide such a high degree of healing that it can even obviate the need for performing surgery on the hemorrhoid;

9. That the above-mentioned differences between Rosenberg and the claimed invention demonstrate the superiority of the claimed invention over Rosenberg;

10. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been obvious to one skilled in art at the time the Application was filed;

11. That Rosenberg moreover does not show the claimed invention. Rather, I find no similarities in the purpose, application, and design of the claimed invention and the technology described in Rosenberg;

12. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

11/4/2009

Date

Sandra L. Curet

Sandra L. Curet

EVIDENCE APPENDIX F

Copy of the Declaration under 37 C.F.R § 1.132 of Doctor
Randolph M. Steinhagen, originally filed by appellant on
November 12, 2009

PATENTS
REB-001 Div

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez

Application No. : 10/696,258 Confirmation No. : 7051

Filed : October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS

Art Unit : 3769

Examiner : David M. Shay

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF RANDOLPH M. STEINHAGEN

Sir:

I, Randolph M. Steinhagen, hereby declare as follows:

1. That I am the Chief of the Division of Colon and Rectal Surgery at Mount Sinai Medical Center located in New York City, New York, and have worked at Mount Sinai Medical Center since 1984. In addition, I have a position as the Professor of Surgery in the Mount Sinai School of Medicine;

2. That I am very familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I

have reviewed the Application and the claims therein which are at issue;

3. That I have moreover worked in a clinical trial to test this claimed invention. The results of this clinical trial indicated that the claimed invention was generally a success and preferred by the subjects of the trial;

4. That I am familiar with the following Rosenberg reference cited by the Examiner, *The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal Wound* (hereinafter referred to as "Rosenberg") that was published in a 1977 issue of *The Diseases of the Colon and Rectum*. It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the Application have been rejected by the Examiner based on Rosenberg;

5. That I have reviewed the Rosenberg publication and have compared the technology described therein to the claimed invention of the Application. Rosenberg describes a "strapping" technique in which an adhesive strapping is strapped to a person's buttocks and crossed in front of the abdomen. This is done to facilitate the healing of a postoperative pilonidal sinus wound;

6. That not only is the adhesive strapping described by Rosenberg applied to a different part of the body than the claimed invention, but the purpose is also different. For example, Rosenberg describes a technique of applying postoperative wound dressings to facilitate the healing of a pilonidal surgical wound. The claimed invention, on the other

hand, includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids. The claimed invention can also provide further benefits, such as obviating the need for a hemorrhoids patient to undergo surgery;

7. That the claimed invention has a unique shape and structure not shown by Rosenberg. The claimed invention can operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient's body. This particular lifting that is provided by the unique shape and structure of the claimed invention can allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects to the inflamed tissue. Moreover, the specific angle at which the claimed invention lifts the inflamed tissue does not hinder movement of a patient's body. The claimed invention can therefore allow a patient to walk, sit, sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application of the claimed invention. Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention;

8. That the above-mentioned differences between Rosenberg and the claimed invention demonstrate the superiority of the claimed invention over Rosenberg;

9. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been

obvious to one skilled in art at the time the Application was filed;

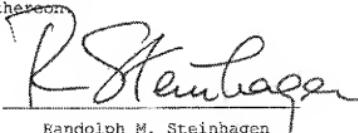
10. That, in my expert opinion, many people could benefit from the claimed invention. The claimed invention can provide benefits such as enhanced healing effects and helping patients avoid surgery, thereby significantly reducing health care costs;

11. That Rosenberg does not show the claimed invention. Nor, to my knowledge, is there any product on the market that is similar to the claimed invention. After comparing Rosenberg with the claimed invention, I have concluded that any supposed similarities between Rosenberg and the claimed invention are minimal at best and negligible;

12. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable b y fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

10/28/2009

Date


Randolph M. Steinhagen

EVIDENCE APPENDIX G

Copy of the Declaration under 37 C.F.R § 1.132 of
Maria Isabel Suárez originally filed by appellant on
November 12, 2009

PATENTS
REB-001 Div

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez

Application No. : 10/696,258 Confirmation No. : 7051

Filed : October 28, 2003

For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS

Art Unit : 3769

Examiner : David M. Shay

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF
Maria Isabel Suárez

Sir:

I, Maria Isabel Suárez, hereby declare as follows:

1. That I was a patient suffering from a Grade 4 hemorrhoid that had become thrombosed. A Grade 4 hemorrhoid is one of the most severe types of hemorrhoids. A thrombosed hemorrhoid is one that has developed a blood clot;

2. That I had tried various suppositories, various creams, Preparation H, cortisone creams such as Peranex, and even pain medications. However, nothing helped to heal the hemorrhoid or provide relief from the pain and hemorrhoid symptoms. Some medications, such as the Peranex, would even burn my skin and further exasperate the situation;

3. That my doctor had treated the hemorrhoid and cut and drained it. Despite this treatment, however, the doctor had assured me that I would need to undergo surgery given the extreme severity of the hemorrhoid;

4. That I am familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I have reviewed the Application and the claims therein which are at issue;

5. That after suffering from the above-mentioned hemorrhoid for 13 days, I tried using the claimed invention of the Application to treat my hemorrhoid. One of my hopes in using the claimed invention was that it would allow me to avoid undergoing surgery;

6. That after wearing the claimed invention for just three days, the hemorrhoid had turned from a dark purple to a healthy, light pink. At this point, I had no pain whatsoever and was completely rehabilitated;

7. That even though I wore the claimed invention continuously throughout the day and night, the claimed invention was comfortable to wear and allowed me to move freely without

any uncomfortable pulling of the skin or muscles and without causing any other discomfort. Rather, I was able to freely sit, stand, walk, and otherwise engage in my routine, daily activities. Additionally, the claimed invention did not show through clothing and thus I was able to wear it even when I was out in public;

8. That by using the claimed invention I was able to immediately return to work. This was especially important to me as I am a working mother of three children and do not have the luxury of taking any sick days. Moreover, the claimed invention was comfortable to wear and did not impede with my ability to perform well or concentrate at work. As such, by allowing me to avoid surgery and return immediately to work, the claimed invention had a dramatic and positive impact on me and my family;

9. That this was one of the most severe hemorrhoids which I had experienced. Regardless, despite the severity of this hemorrhoid, my body was able to heal very rapidly due to the claimed invention. Moreover, because of the claimed invention, I was able to avoid going through a painful and costly surgery and was able to return immediately to work;

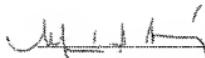
10. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such

Application No.: 10/696,258
Docket No.: REB-001 Div

willful false statements may jeopardize the validity of the application and any patent issued thereon.

11/16/09

Date



Maria Isabel Suárez

(x) Related Proceedings Appendix

None.